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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 25, 2002, from 8:30 a.m. to 5:30 p.m., and February 26, 2002, from 8 a.m. to 5 p.m.:

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Nancy Chamberlin, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail: CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 25, 2002, the subcommittee will: (1) Identify and define technology and regulatory uncertainties/hurdles, possible solutions, and strategies for the successful implementation of process analytical technologies (PATs) in pharmaceutical development and manufacturing; (2) discuss general principles for regulatory application of PATs including principles

of method validation, specifications, use and validation of chemometric tools, and feasibility of parametric release concept; and (3) discuss the need for a general FDA guidance to facilitate the implementation of PATs.

On February 26, 2002, the subcommittee will discuss strategies to explore issues in the following four focus areas: (1) Product and process development, (2) process and analytical validation, (3) chemometrics, and (4) process analytical technologies, applications and benefits.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by February 15, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 25, 2002, and between approximately 1:30 p.m. and 2 p.m. on February 26, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 15, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nancy Chamberlin at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 1-31-02

January 31, 2002.

Linda A. Suydam

Linda A. Suydam
Senior Associate Commissioner.

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